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CENTRAL FAX CENTER

JUN 20 2007

Appl. No.: 10/565,690

Amdt. Dated June 20, 2007

Response to Office Action Mailed April 23, 2007

**REMARKS:**

In the second, final Office Action, mailed April 23, 2007, the Examiner has withdrawn all prior rejections but now objects to the form of specific phrases or elements in claims 1, 2, 6, 7, 9, and 16-18 and so has rejected all the claims under 35 USC §112. Claims 1-6 and 9-15 are now or again rejected as anticipated by the previously cited Sanders '399 patent; claims 7 and 16-18 are again rejected as obvious on Sanders in view of the previously cited Kane application publication '492; and claims 8 and 19-20 are again rejected as obvious on Sanders in view of previously-cited Cooley '925 patent.

By this Response, claims 1-20 currently pending have been amended to improve their forms, including now removing all of the reference numerals, without any substantial narrowing of their subject matter except as to now meeting international and federal requirements for shipping of hazardous substances and products, such as IATA and US DOT regulations - a recitation giving life and meaning to the claims. The claims are again distinguished from the cited prior art, which is directed to different problems than the present invention and so have different structures that do not anticipate or make obvious the now even more-clearly-claimed matter of the present invention.

The present invention is directed to a single-use, flexible shipping container with a secure, double seal, for containing hazardous biologic and other materials, the container meeting official requirements, such as IATA and US DOT regulations, for shipping the container and hazardous materials therein by commercial air transport. The package of this disclosure and

claims is a single use package, to be filled, sealed, shipped, opened and emptied in a controlled environment, and then discarded and processed for safe disposal. Principal reference Sanders '399 is directed not to approved shipping containers but to a reusable, re-sealable pouch having only a single seal over its slit 17. Kane similarly shows not an approved shipping container but a reusable, re-sealable consumer food package adapted for forming, filling, and sealing at high speeds in production lines, with no comments about security of the contents during shipping. Cooley '925 discloses an authenticating and tamper-evident label involving opaque layers that turn transparent upon tampering, but not for securely containing hazardous materials during air transport. None of the references, singly or together, make the claimed invention non-novel or obvious.

According to the present disclosure, a single-use package is provided having a slot 18 for insertion of a hazardous item such as a vial of biologic fluid, a tissue specimen, or the like, loss or spillage of which would be dangerous to an aircraft and its crew and to baggage or freight handlers. A portion 20 of a double-sided adhesive strip 10 is pre-affixed on one of its sides 12, near one of its ends, to the outer wall 2, 9 of the package adjacent the slot 18, with a detachable protective strip 15 covering the balance 14 of that side of the strip (Fig. 2). After the product is inserted, the protective strip 15 is removed from the wall-side portion of the strip 10 and that one side 14 is pressed onto the outer wall 9, 23 of the package and across the slot 18, sealing the product into the package. Then the other protective strip 17 on the other side of the strip 10 is removed and the top 4 of the package is folded over at the slot 5, so that the adhesive strip 10 is bent back onto itself with the end 13 of the strip also adhering to the wall 2, 9 of the package below the other end 20 of the adhesive strip. This forms the double seal that is used to implement packaging in a novel, unobvious, and most useful way to comply as required with the international and federal specifications; indeed the packaging according to this disclosure has now successfully passed the IATA and US DOT certification tests.

**Rejections of Claims 1-6 and 9-15 on Sanders '399 patent, under 35 USC §102(b).**

The Sanders '399 patent is not directed to providing a single-use or safe, leakproof container for secure transport of hazardous materials, as is now required by all the claims. Base claim 1 herein requires the formation of a double seal, whereby the slot is adapted to be doubly sealed along its entire length on the outer wall of the envelope by, first, the first face of the adhesive strip and also, second, by the second face of the adhesive strip bonding to the outer wall of the envelope adjacent and beyond the end of the first face of the adhesive strip. In contrast, Sanders' arrangement does not form a double seal over the entirety of the opening of the slit 17 through the outer wall, for instance.

Sanders provides a re-useable tape seal with a finger tab at 23 for reopening the adhesive joint, in contrast to the single-use, double seal of the present invention. See the Sanders disclosure, at col. 4 lines 1-46 (quoted in the first response). The Sanders package is only "substantially" airtight, rather than "air-impervious" as required in claim 1 herein. The Sanders package is "easily openable" as by internal pressure, rather than being "adapted, when sealed, to resist leakage of contents when subjected to a raised internal pressure" as set forth in claim 1 herein. These properties of the Sanders package are simply not appropriate for hazardous material transport. No suggestion or teaching appears in Sanders that the upper surface of the sealing tape 21 in Figs. 1-2 has adhesive thereon, as in the "two parallel adhesive faces" set forth and described in the limitations of claim 1 herein.

Figures 12-13 of Sanders do show a double-sided tape 50, with silicone release paper 52 on the upper side thereof in Fig. 12 (see col. 7, ll. 4-42). The tape 50 then adheres to itself across the slit 17 as is required in the present invention, but this comprises only a single seal across the slit 17 as in Figure 12 of Sanders, not the double seal (*see* 12, 22 of application Fig. 4) required by the final paragraph of claim 1 herein, which, in contrast to the Sanders package, meets international and federal air shipping regulations. This disclosure in Sanders is properly not relied on by the Examiner in his consideration of the claims of the present application.

The Examiner's citation of Sanders' "substrate" 21, in Fig. 1, as a "detachable protective strip" (para. 9 of the action) that corresponds to the protective strip 17 of present claim 1 and Fig. 1, is incorrect. Substrate 21 of Sanders is disclosed as "adhesive tape", not release paper. As stated in the Sanders disclosure cited above, the adhesive 19 of Sanders is part of adhesive tape 21, being on the under-surface 22 of the substrate 21; adhesive 19 however adheres more strongly to the surface 18 of the package than to the surface 22 of the substrate 21. Therefore, as the substrate 21 is peeled upwardly to open the slit 17, the rightward portion of the adhesive in Fig. 2 of Sanders remains attached to the wall 18, while the leftward portion remains attached to both the substrate 21 and the wall 18, leftward of the slit 17. There is no adhesive on top of the substrate 21, so folding the package 10 and the substrate 21 back on themselves at the slit 17, as is done in Fig. 4 of the present disclosure (at slot 5) - even if done, contrary to all suggestions in Sanders - would not and cannot result in the double seal that is required by claim 1, final paragraph, and by international and federal regulations for air transport of hazardous materials.

Sanders thus also has no protective release strip, as in the "second detachable protective strip" 15 of claim 1 herein, on a lower surface of Sanders' adhesive 19, to keep his slit 17 open for insertion of product. Thus, there is nothing in Sanders corresponding to the larger, "first, detachable protective strip" 17 of Fig. 1 and claim 1 of the present application. Further, nothing in Sanders corresponds to the detachable protective strip below adhesive 19 rightwardly of the slit 17 in Sanders as is claimed in the present case. Further, there is nothing in Sanders corresponding to the set of two parallel adhesive surfaces of the strip as defined in claim 1 of this application. Claim 1 is novel over Sanders.

The Examiner is incorrect that Sanders's tape 20 overlaps itself in Fig. 10, as the folded-over web 46 prevents the tape from the left engaging the end of the tape located under that web 46. This is why Sanders can claim only "substantial" air-tightness for his package.

The double sealing of the present disclosure and claims is necessary to sustain the seal as against the relative internal pressures to be encountered in air transport; "easy" opening and

spillage from the Sanders package in the intended use, as shown in his "substantially airtight" admission in the specification, is wholly unacceptable. The structures of the unfilled bag as per claim 1 here and of the filled bag of method claim 9 are simply not provided by Sanders and are patentably novel over Sanders.

Independent claim 1 is allowable over Sanders since these several fundamental elements are not shown in nor suggested by Sanders, alone or in combination with the other art cited, nor within the ordinary skill of the art to add to or engraft onto Sanders' disclosure. Providing these elements in this combination is simply not within the province of one of ordinary skill in the art to devise and implement, but requires invention. The remaining claims 2-20 are allowable as all depend from or incorporate the novel and unobvious subject matter of claim 1.

The Examiner's rejection of claim 9 of the application as also anticipated by Sanders, based solely on the analysis shown above as faulty in regard to claim 1, is equally unavailing to show anticipation of claim 9. Sanders has no "first protective strip covering the second zone of the adhesive strip", as is shown above, and Sanders discloses no second protective strip that may be removed from the first or outer face of the adhesive substrate, as the Examiner asserts. The Examiner's citation to Col. 7, ll. 4-22 of Sanders is inapposite to this rejection, as that text of Sanders refers to Figs. 10 and 11, which have nothing to do with Figs. 1-2 of Sanders; thus, this argument of the Examiner is not understood. Picking out unrelated bits and pieces of a reference to try to show anticipation is improper.

The rejections of independent claim 1 and method claim 9 of the application as anticipated by Sanders '399 patent are unwarranted. These rejections should be reconsidered and withdrawn, together with the similar rejections of claims 2-6 and 10-15 dependent from them.

**Rejections of Claims 7 and 16-18 on Sanders '399 in view of Kane, under 35 USC §103(a).**

Claims 7 and 16-18 of the present application claim an envelope comprising an outer wall comprising an outer sheet having oriented polyamide in an outer layer, and a polyethylene inner layer. Since claim 1 is allowable, as demonstrated above, these claims are also allowable as incorporating the novel structure defined there.

These claims also are independently patentably non-obvious over the combination of art applied in paragraph 10 of the second, final action. Although Kane does disclose each of oriented polyamide in an outer layer of an envelope and various specific polyethylenes in an inner layer, such "menu" disclosure, even in related-art patents, is frowned upon. *Medtronic Navigation v. Brainlab*, Fed. Cir. (06-1289) (non-precedential). Kane and Sanders together do not suggest use of such materials in the structure defined in these claims of the present application, for providing a secure, internationally- and federally-approvable secondary packaging that is leakproof under air transport conditions. Such combination is not within the ordinary skill of the art, either.

**Rejections of Claims 8 and 19-20 on Sanders '399 in view of Cooley '925.**

Claims 8 and 19-20 recite that the adhesive strip used to double-seal the envelope comprises at least one sheet of synthetic olefin polymer covered on two sides with a rubber-based adhesive. Since claim 1 is allowable, as demonstrated above, these claims are also allowable as incorporating the novel structure defined there.

These claims also are independently patentably non-obvious over the combination of art applied in paragraph 11 of the action. Although Cooley does disclose each of synthetic olefin polymer and rubber-based adhesive in the text cited, such "menu" disclosure in unrelated art (Cooley discloses tamper-evident seals, not recloseable seals as does Sanders) is frowned upon. *Medtronic Navigation v. Brainlab*, Fed. Cir. (06-1289) (non-precedential). Cooley and

Sanders together do not suggest use of such materials in the structure defined in claims 8 and 19-20 of the present application, for providing a secure, internationally- and federally-approvable secondary packaging that is leakproof under air transport conditions, as required. Such a combination was not available to one of ordinary skill in the art, either.

**“Answers to Applicant’s Arguments” Rebutted.**

The Examiner in paragraphs 12-17 of the Office action seeks to explain why the case was not allowable after the first amendment. Each of these explanations is now overcome or inapposite in view of the amendments made and explanations above.

As to paras. 12, 13, 15, and 17 in the Office action, meeting the international and federal specification requirements - including for instance the IATA and US-DOT requirements - and providing a double seal over the entire length of the slot are now expressly recited in claim 1 and thus are incorporated into all the claims.

As to para. 14, applicants have made clear, in the text of claim 1 as previously and now again presented, and in their arguments above, the roles of the first and the second detachable protective strips 15 and 17. Applicants claim not an “overlap” of adhesive over itself for a small portion of the slot for sealing same but that the double seal extends the full length of the slot (see claim 1, final paragraph). Indeed, a double seal that exists for only a portion of a slot is hardly an effective double seal and would not meet IATA or US-DOT specifications.

As to para. 16, Cooley discloses a tamper indicating label, not a secure package that is resistant to leakage under IATA and US-DOT test conditions. One of ordinary skill in the art would not look to Cooley to solve leakage problems left by the Sanders disclosure. Applicants have no issue with combining related art as Kane and Sanders, but Cooley is unrelated; even if Cooley were combined with Sanders, however, it does not suggest or motivate making the present invention in any respect. Such a combination was not, in any event, available to one of ordinary skill in the art.

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**CENTRAL FAX CENTER****JUN 20 2007****CONCLUSION**

The art cited does not anticipate or render obvious the combinations of elements and functions recited in any of claims 1-20 of the present application. Sanders '399 lacks the elongated "double-sticky" tape and protective covers arranged with the package or envelope as in the present disclosure and claims, and the other art cited does not make up for that shortfall. Each and all of claims 1-20 should be reconsidered and now allowed for issuance. Favorable reconsideration is earnestly requested. If any matters may be resolved in a telephone conference, the Examiner is requested to telephone undersigned counsel for applicant.

*Deposit Account Charge Authorization and Extension Request.* The Commissioner is hereby authorized to charge any fees associated with this communication to our Deposit Account No. 50-0305, including any required fees for any required extension of time under 37 CFR §1.136, which is hereby requested.

Respectfully submitted,

By: 

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